October 24, 2005

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: Director, NIH

SUBJECT: Federal Managers' Financial Integrity Act (FMFIA) of 1982 – *Annual Assurances of Compliance* – INFORMATION

PURPOSE

The purpose of this memorandum is to provide the necessary assurances of and information on National Institutes of Health (NIH) compliance with the FMFIA (31 U.S.C. 3512). It is prepared in accordance with Office of Management and Budget (OMB) fiscal year (FY) 2005 reporting requirements and covers Section 2, *Internal Controls,* and Section 4, *Financial Systems.*

I, Elias A. Zerhouni, NIH Director, state and assure that to the best of my knowledge:

(1) The system of internal controls of this agency, except as indicated under (5), is functioning and provides reasonable assurance as to the efficiency and effectiveness of programs and operations; the reliability of financial and performance information; and compliance with laws and regulations. These controls satisfy the requirements of the FMFIA § 2.

(2) The financial management systems of this agency, except as indicated under (5), provide reasonable assurances that obligations and costs are in compliance with applicable law and performance data and proprietary and budgetary accounting transactions applicable to the agency are properly recorded and accounted for to permit the timely preparation of accounts and reliable performance information. The financial control at this agency satisfies the requirements of the FMFIA § 4.

(3) The system of internal controls of this agency that relates to the security of financial management systems and performance and other financial data, except as indicated under (5), provides protections commensurate with the risk and magnitude of harm resulting from loss, misuse, or unauthorized access and satisfies the requirements of § 5131 of the Clinger-Cohen Act of 1996, § 5 and 6 of the Computer Security Act, and § 3533(D)(2) of the Government Information Security Reform Act.

(4) The financial management systems of this agency, except as indicated under (5), provide this agency with reliable, timely, complete, and consistent performance and other financial information to make decisions and efficiently operate and evaluate programs and satisfy the requirements of the Federal Financial Management Improvement Act § 803(a), the Government Performance and Results Act, and *OMB Circular No. A-11 Preparation and Submission of Budget Estimates*. A remediation plan under FMFIA ( ) is (X) is not required.

(5) I am monitoring and employing techniques that mitigate the material weaknesses, as follows:

Description of material weakness	Current status	Resolution target date
Financial Reporting Systems	Corrections in process	2007 or completion of the NBRSS

ASSURANCE STATEMENT, SECTION 2

We are committed to ensuring effective management controls and clearly demonstrating and documenting them in its extramural, intramural, and administrative program areas. During FY 2005, we continued to successfully integrate management controls into program and administrative areas in support of our biomedical and behavioral research mission. We use a multifaceted approach to evaluate the efficacy of our management controls, which includes Management Control Reviews, Alternative Management Control Reviews, General Accounting Office (GAO) Reviews, Office of Inspector General Audits, Corrective Action Reviews, Corrective Action Plans, Program Evaluations, and Management Reviews conducted by both internal and external groups.

A total of 234 program reviews—42 intramural, 99 extramural, and 93 administrative—were ongoing or completed at NIH in FY 2005 (see enclosure E for an inventory of the reviews). In addition, we anticipate that the NIH Division of Program Integrity (DPI) will open 80 new cases, review 98 cases that were opened in prior fiscal years, and close 100 cases. These reviews include an evaluation of systemic controls when related

management controls are found to be lacking or ineffective.

A major review conducted by the NIH Division of Program Integrity in fiscal year 2005 was the NIH Ethics Review. The Division of Program Integrity reviewed the activities of 103 scientists to determine whether they had appropriately participated in outside activities with biotechnology or pharmaceutical companies. Cases of individuals who violated regulations or policies were referred to NIH management for administrative action. In addition, the NIH Ethics Office is strengthening management controls for the ethics program.

Below are examples of proactive reviews that have improved or will enhance management controls for NIH's intramural, extramural, and administrative activities.

INTRAMURAL ACTIVITIES

Intramural Program Reviews

In March 2005, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Blue Ribbon Panel submitted its report evaluating the Intramural Research Program. By May 2005, the NIDDK Director, Scientific Director, and Clinical Director responded with an Implementation Plan based on the Blue Ribbon Panel's recommendations. The NIH Deputy Director for Intramural Research (DDIR) reviewed both and was satisfied with NIDDK's response. In September 2004, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) put together and convened a Blue Ribbon Panel on Intramural Research to provide recommendations on the planning and development of an intramural research program within the NIBIB. The DDIR reviewed the final report from the Panel's meeting, and NIBIB is implementing the recommendations.

The newly formed Advisory Board for Clinical Research (ABCR) conducted its first meeting in September 2004, followed by meetings in January and March of 2005. The Board developed a Work Plan, which included long-range goals for revising the NIH intramural clinical research oversight structure; developing training and career pathways in patient-oriented research; emphasizing the study of rare diseases at the Clinical Center; and promoting a strong emphasis on pathophysiology and novel therapeutics. The ABCR also agreed on the establishment of five working groups: Research Opportunities, Operations and Planning, Careers in Clinical Research, Finance, and Executive. The ABCR has scheduled meetings through 2007.

The DDIR chaired the annual public meeting of the Chairs of the NIH Boards of Scientific Counselors (BSCs) on March 14, 2005. BSCs are duly constituted Federal advisory committees established to advise the Institutes and Centers (ICs) on the quality of the intramural research being conducted. The DDIR discussed the recommendations made by the BSC Chairs with the Scientific Directors for their consideration.

The BSC will hold its next meeting in the spring of 2006.

Animal Care and Use

The NIH has three standing oversight subcommittees of the Animal Research Advisory Committee that are charged with reviewing the scope and implementation of three trans-NIH programs: occupational safety and health, centralized training, and security and disaster preparedness. Since the last Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) peer review site visit in 2002, the subcommittees have issued three annual series of recommendations to further improve practices involving the delivery of the three trans-NIH services. Upon receipt of earlier subcommittee recommendations, the AAALAC awarded Full Accreditation to the NIH Intramural Research Program in January 2003.

The IC Animal Care and Use Committees oversee all intramural research involving animals and conduct semiannual in-depth reviews of all aspects of NIH animal care and use programs. These reviews include not only the examination of facilities and animal procedures managed by the ICs, but also the adequacy and interrelationship of support services, which include occupational safety and health and engineering services critical to the safe and efficient operation and maintenance of animal research facilities.

The triennial AAALAC peer review site visit was held on July 25 - 29, 2005.

Intramural Assessment of Management Controls

The Intramural Assessment of Management Controls is an annual process that requires the Scientific Director of each IC to carry out a self-assessment of management controls. The Office of Intramural Research (OIR) distributes the Annual Intramural Self Assessment of Management Controls survey and, reviews and analyzes the IC submissions to ensure that effective management controls are fully integrated into intramural and administrative program areas.

Graduate Medical Education

The Accreditation Council for Graduate Medical Education (ACGME) reaccredited the programs for Medical Genetics and for the Blood Bank. Mandated internal reviews were conducted for Rheumatology, Cytopathology, and Anatomic Pathology.

Continuing Medical Education

In April 2005, the NIH submitted its annual report to the Accreditation Council for Continuing Medical Education (ACCME). Our continuing medical education program accredited 318 activities, representing 2,829 hours of instruction and serving 28,184 physicians and 26,987 nonphysicians locally, nationally, and internationally.

Continuing Education

In June 2005, the Continuing Professional Education Committee of the American Psychological Association granted the NIH Continuing Education Program for psychologists continued approval. A total of 10 activities provided 240 credits of continuing education to 672 psychologists.

Technology Transfer Activities

As part of its "Work Plan for Fiscal Year 2004," the HHS Office of Inspector General (OIG), Office of Audit Services, conducted an audit of NIH royalty income from intramural inventions. The audit began in June 2004 and the initial reviews concluded in February 2005. The review was to determine whether NIH received the royalty income to which it was entitled, royalties were calculated correctly, and payments were received in a timely manner. NIH has not yet received the OIG's recommendations or initial report.

EXTRAMURAL ACTIVITIES

Proactive Compliance Site Visits

The findings of proactive compliance site visits it conducted in FY 2004, provided a basis for the NIH Office of Extramural Research (OER) to issue a notice in the *NIH Guide for Grants and Contracts* reminding grantees of the conflict of interest requirement for all NIH-supported institutions: see http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-05-013.html.

In FY 2005, the NIH Office of Extramural Research (OER) is developing a plan for refocusing the scope of its site visit program to target the areas of conflict of interest and patent and invention reporting. These site visits will be used to evaluate compliance and to gather data on policy implementation.

Grants Oversight Processes

In FY 2005, OER is analyzing the responses from the Management Controls Assessment Questionnaire for Extramural Research. The Management Controls Assessment Questionnaire is used to evaluate management controls for extramural research, including review, program, and grants management, in the NIH ICs. This tool, which was initially administered in FY2004, was designed to assist ICs identify potential areas for improved compliance with both NIH and their own established policies and procedures. Deficiencies will be brought to the attention of the NIH ICs for resolution and policy clarifications will be issued as appropriate.

Monitoring of Human and Animal Data in Progress Reports

In FY 2005, OER more fully established a process of quarterly reviews of electronic progress report submissions to ensure the currency of human subject/vertebrate animal committee approval dates. This data is being used to determine compliance and is helping NIH to view institutional activities as a whole rather than only seeing grant-by-grant issues.

OER Assessment

In FY 2005 the NIH Deputy Director for Extramural Research conducted an organization assessment of the OER to identify specific actions OER could take to strengthen the delivery of its programs and services. In response to the study, the Office will be undergoing a reorganization to facilitate planning, evaluation, and communication of extramural policies and programs and will be seeking resources to improve its operations.

National Research Service Awards Payback Center Outcomes

A 1999 Office of Inspector General audit of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program identified problems with the program's database. In response, Payback Service Center functions and responsibilities were transferred from the National Institute of General Medical Sciences to the Office of Extramural Research within the Office of the Director, NIH.

Since the transfer, the NRSA Payback Service Center has processed and closed 1,194 trainee and fellowship obligation files in 2001; 2,150 files in 2002; 3,340 files in 2003; 2,587 files in FY 2004, and, to date, 2,024 files in FY 2005. A total of 1,307 delinquent trainee and fellowship files for these same years were forwarded to the Office of Financial Management for further processing, after the NRSA Payback Office made multiple attempts to obtain required follow-up information from the trainees and fellows involved. Total amounts collected from NRSA recipient payback reimbursements were $401,065 in FY 2001, $474,499 in FY 2002, $566,833 in FY 2003 and $339,156 in FY 2004. So far, the NRSA Payback Office has forwarded 224 files to OFM for processing in FY 2005. The total amount collected from OFM as of June 2005 is $202,600.

NIH Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research

On May 2, 2005, the NIH implemented a new policy on enhancing public access to archived publications resulting from NIH-funded research (Public Access Policy). We request NIH-funded investigators to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part,

with direct costs from NIH. We established an NIH Public Access Policy Working Group of the NLM Board of Regents on May 11, 2005. The Working Group is composed of stakeholders that will advise the Board of Regents on implementation and assess progress in meeting the goals of the NIH Public Access Policy. We will modify and enhance the Policy as needed, with the Working Group, or a permanent subcommittee of the Board, providing ongoing advice on improvements.

Research Training and New Investigators

The National Research Council (NRC) of the National Academies of Science issued two reports in 2005 about the research training and career development of our Nation's next generation of biomedical, behavioral, and clinical research scientists. The reports evaluated needs for research personnel in the United States and provided

recommendations to help new investigators make the transition to independent scientists with stable research support. In response to the reports, we have established internal NIH committees to assess the NRC recommendations. We anticipate that the committees will develop a list of action items to facilitate an investigator's ability to receive an independent research award (R01) earlier in his or her research career. The committees will also develop strategies that have the potential to increase and maintain a healthy cohort of new and talented, NIH-supported, independent investigators.

Reporting of Patents and Inventions

In FY 2005, we continued to increase efforts to improve grantee and contractor patent and invention reporting through expanded outreach and technical assistance to our internal and external research partners. Since 2004, we have worked towards makiing i-Edison the Federal-wide system for invention reporting compliance, increasing the number of Federal Government Agencies using the system from 21 in 2004 to 25 in 2005.

Office of Electronic Research and Reports Management

The Gartner Group did an Independent Verification and Validation (IV&V) baseline review of NIH's electronic Research Administration (eRA) program. They began the review in FY 2004 and completed it in FY 2005; our actions to implement their recommendations are under way. An internal review within the OER recommended a merger of the eRA and the Office of Reports and Analysis to create the Office of Electronic Research and Reports Management (OERRM). The reorganization provided a means of implementing many of the IV&V recommendations. The new OERRM organizational structure is more aligned with the OER mission, is more customer service oriented, has more accountability to internal management and external users of the IT system, will use best practices for program management, and will have improved cost tracking and budget planning.

Substantial progress has been made on the implementation of Public Law 106-107, the Federal Financial Assistance Management Improvement Act, during FY 2005. For instance, we now do many of the paper-based transactions associated with the administration of research grants electronically. Externally, applicants can find announcements and make applications through Grants.Gov. Internally, we receive all grant applications electronically or we convert them to electronic format for internal receipt, referral, and review. The Internet Assisted Review module is fully operational and the creation and transmission of millions of pages of paper has been eliminated. We now use electronic notification to notify applicants, NIH personnel, and grantees of actions taken and actions required in the grants administration process. In addition, we now receive status reports from grantees electronically, and the increased use of electronic transfer of information has improved the timeliness and accuracy of our grants financial data.

ASSURANCE STATEMENT - SECTION 4

NIH financial systems, as a whole, satisfy most policies and standards prescribed for executive agencies in developing, operating, evaluating, and reporting on financial management systems as defined in OMB Circular A-127, *Financial Management Systems*, and OMB's *Implementation Guidance for the Federal Financial Management Improvement Act (FFMIA) of 1996*.

There are instances, however, in which our financial systems, including the financial portion of mixed systems, do not fully conform to all Government-wide standards. These standards require that agency financial management systems comply with the following requirements:

- Systems must use an agency-wide financial information classification structure.
- All financial and the financial portion of mixed systems must be integrated.
- Systems must use the U.S. Government Standard General Ledger at the transaction level.
- Systems must comply with applicable Federal accounting standards.
- Systems must meet all financial reporting requirements.
- Systems must capture and produce financial data to measure program performance.
- Systems must comply with the functional requirements of the Joint Financial Management Improvement Program.
- Systems must ensure that internal controls exist for all inputs, processing, and output functions.

Ernst & Young reported in its FY 2004 Report of Independent Auditors on Compliance with Laws and Regulations that it performed tests to determine whether NIH financial management systems substantially comply with Federal financial management

system requirements, applicable accounting standards, and the U.S. Standard General Ledger at the transaction level. The results of its tests disclosed instances in which NIH's financial management systems did not substantially comply with certain requirements.

As part of the FY 2005 Chief Financial Officer/Government Management Reform Act audit, we assessed our compliance with financial system requirements and with the FFMIA, and we concluded that our financial systems, including mixed systems, do not fully conform to all Government-wide standards required by OMB Circular A-127. To address these issues, we have strengthened compensating controls and revised the accounting system closing process.

Some mixed systems do not provide financial transactions to the central system using consistent processing rules. In addition, some systems are not fully and seamlessly integrated but are otherwise linked with the system. For example, the property management information system does not comply with financial systems requirements.

The NIH Chief Financial Officer five-year plan indicated that NIH did not fully comply with all financial systems requirements.

REMEDIATION PLAN

To address these issues, we—

- launched a review and assessment of how NIH transacts business among all internal activities and customers to identify system integration and accounting requirements (expected completion 2007) and
- awarded a contract for an NIH-wide business system, to include a Joint Financial Management Improvement Program-approved accounting system (expected completion 2007).

MAJOR REVIEWS

We initiated a review to address and resolve the material weaknesses cited in the audit of HHS' FY 2004 financial statements. The review included NIH and contract audit staff and focused on the methodology and discipline applied to our fiscal year closing process. As a result of these efforts, we have implemented numerous additional analyses and reconciliations; we have implemented a new, more disciplined and controlled process to prepare the trial balances from which our financial statements are prepared; and we have identified additional areas of potential improvement on which we have already begun work. Also, we plan to validate or change certain internal processes and provide significant training to staff. This effort will result in benefits to accounting operations and to the administrative operations of ICs.

The Office of Financial Management, working with the NIH Center for Information Technology, has implemented a new Web-based tool that allows staff to analyze on-line all general ledger accounts individually and by transaction codes. This has allowed us to correct and compensate for some of the deficiencies noted by auditors. The information is more reliable and available in a timely manner for review and reporting.

FMFIA REPORT

The FMFIA report also includes the following documents and is available from Ms. Suzanne J. Servis, Director, Office of Management Assessment, Office of the Director. She can be reached at (301) 496-1873.

Enclosure *A* - *Statistical Summary of Performance*

Enclosure *B* - *Progress Report of High Risk Areas* (none)

Enclosure *C* - *Schedule of Corrective Actions for Pending Material Weaknesses* (none)

Enclosure *D* - *Schedule of Pending Material Non-Conformances (Section 4)* (none)

Enclosure *E* - *Inventory of FY 2005 Reviews*

/s/

Elias A. Zerhouni, M.D.

Enclosures